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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/646,950	12/08/2000	Colin Watts	ERP01.004A	2538
20995 7590 07/01/2008 KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614				
EXAMINER VANDERVEGT, FRANCOIS P				
ART UNIT		PAPER NUMBER		
1644				
NOTIFICATION DATE		DELIVERY MODE		
07/01/2008		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com  
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### Office Action Summary

**Application No.**

09/646,950

**Applicant(s)**

WATTS, COLIN

**Examiner**

F. Pierre VanderVegt

**Art Unit**

1644

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 15, 16, 18-20, 38, 41, 42, 52-54, 56, 60, 61, 69 and 71-74 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 38, 41, 42, 52-54, 56, 61 and 69 is/are allowed.
- 6) ☒ Claim(s) 71 and 74 is/are rejected.
- 7) ☒ Claim(s) 15, 16, 18-20, 60, 72 and 73 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

This application is a rule 371 continuation of PCT Serial Number PCT/GB99/00963.

Claims 1-14, 17, 21-37, 39, 40, 43-51, 55, 57-59, 62-68 and 70 have been canceled.

New claims 71-74 have been added.

Claims 15, 16, 18-20, 38, 41, 42, 52-54, 56, 60, 61, 69 and 71-74 are currently pending and are the subject of examination in the present Office Action.

In view of Applicant's amendments filed December 28, 2007 no outstanding ground of rejection is maintained.

The following NEW GROUNDS of rejection have been necessitated by Applicant's amendment.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 71 and 74 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an inhibitor of asparaginyl endopeptidase that is a competitive inhibitor comprising a peptide selected from the group consisting of Ala-Glu-Asn-Lys-NH (AENK) (SEQ ID NO: 1) and Lys-Asn-Asn-Glu-NH (KNNE) (SEQ ID NO: 2); or an inhibitor of asparaginyl endopeptidase that a non-competitive inhibitor of asparaginyl endopeptidase which comprises an asparagine residue to which is attached a group capable of reacting with active site cysteine of asparaginyl endopeptidase and forming a covalent complex therewith, does not reasonably provide enablement for the full scope of inhibitors of asparaginyl endopeptidase. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

Applicant has amended the claims to expand the scope of asparaginyl endopeptidase inhibitors used in the claimed method to include ALL inhibitors of asparaginyl endopeptidase. The claims read upon the use of any inhibitor of asparaginyl endopeptidase in the claimed method. However, the specification discloses only two specific terminally blocked tetramer peptides and peptides that satisfy the chemical formula B1-(X)<sub>n</sub>-Asn-Q, for example. The specification does not disclose the use or suitability of any other type of asparaginyl endopeptidase inhibitor for administration to a patient for inhibition of

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enzyme activity and subsequent immune responsiveness. Additionally, other than the disclosed peptides that bind and interfere with the asparagine-cysteine cleavage site of the enzyme, the specification does not teach the artisan how to make any other type of inhibitor of the asparaginyl endopeptidase enzyme. The term includes in scope ALL agents or compounds that would inhibit the enzyme, such as potential inorganic or organic small molecules, carbohydrates or immunoglobulins, for example, even inclusive of inhibitors of transcription such as DNA-binding proteins or antisense molecules for example. However, the specification fails to disclose any of these molecules and does not teach the artisan how to make or how to use any of them.

In view of the quantity of experimentation necessary, the limited working examples, the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims, it would take undue trials and errors to practice the claimed invention and this is not sanctioned by the statute.

#### Conclusion

2. Claims 38, 41, 42, 52-54, 56, 61 and 69 are allowed.
3. Claims 15, 16, 18-20, 60, 72 and 73 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571)272-0852. The examiner can normally be reached on M-Th 6:30-4:00 and Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on (571) 272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

F. Pierre VanderVegt, Ph.D. /PV/  
Patent Examiner  
June 18, 2008

/David A Saunders/  
Primary Examiner, Art Unit 1644